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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/609,417	07/01/2003	Denis Leclerc	1398-104US	9472

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EXAMINER	
BOESEN, AGNIESZKA	
ART UNIT	**PAPER NUMBER**
1648	

DATE MAILED: 09/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/609,417	LECLERC ET AL.	
	Examiner	Art Unit	
	Agnieszka Boesen	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 June 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20-25 and 27-43* is/are pending in the application.

4a) Of the above claim(s) *31,40 and 41* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20-25,27-30,32-39, 42 and 43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *June 20, 2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The Amendment filed June 20, 2006 in response to the Office Action of December 20, 2005 is acknowledged and entered. The Declaration under 37 C.F.R. §1.132 of inventor Denis Leclerc is acknowledged. Claim 43 has been added. Claims 20-25, 27-30, 32-39, 42, and 43 are under examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

The Examiner of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Examiner Agnieszka Boesen Group Art Unit 1648.

Information Disclosure Statement

2. The Supplemental Information Disclosure Statement received June 20, 2006 has been considered.

Claim Rejections - 35 USC § 112

3. The rejection of claims 20-39, and 42 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which

Applicant regards as the invention is **withdrawn** in view of Applicant's arguments and amendments to the claims.

4. **However, upon further consideration claim 20 is rejected under 35 U.S.C. 112, second paragraph**, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention with regard to recitation of the phrase "derived."

The term "derived" is not one which has a universally accepted meaning in the art nor is it one which has been adequately defined in the specification. The primary deficiency in the use of this phrase is the absence of an ascertainable meaning for said phrase. Since it is unclear what are the components of the PapMV coat protein from which the VLP is derived, there is no way for a person of skill in the art to ascribe a discrete and identifiable class of components to said phrase. Further, it is not clear whether the components of the PapMV coat protein are formed by attachment of a detectable marker, therapeutic molecule, some other molecule or by altering the amino acid sequence, for example. In addition, since the term "derived" does not appear to be clearly defined in the specification, the term can encompass proteins with amino acid substitutions, insertions, or deletions, or chemically derivatized molecules. In absence of a single defined art recognized meaning for the phrase and lacking a definition of the term in the specification, one of skill in the art could not determine the metes and bounds of the claims.

5. Claims 20-31, 33-39, and 42 were rejected for failing to comply with the enablement requirement under 35 U.S.C. 112, first paragraph, regarding "potentiating an immune response." Applicant's arguments and the Inventor's Declaration have been fully considered.

- In points 1-5 of the declaration, Dr. Leclerc identifies himself as an inventor of the claimed subject matter and states that he is familiar with the prosecution history of the instant application, in particular, the enablement rejection set forth in the Office Action of Decmeber 20, 2005.
- In points 6-8, Dr. Leclerc states that the PapMV VLPs are capable of inducing a humoral response, a TH1 immune response, and cellular immunity. Dr. Leclerc points to Example II, page 18, page 5, line 13 to page 6, line 4, and page 8, lines 10-26. Dr. Leclerc notes that at the time of filing, it was well known in the art that adjuvants can augment both humoral and cellular responses.
    - In response, the Office acknowledges and agrees that adjuvants are known to be capable of augmenting humoral and cellular immune responses and that papMV VLPs could elicit immune responses other than humoral immune response and one of ordinary skill in the art could readily test for this ability using standard techniques.
- In points 9-11, Dr. Leclerc discloses the construction of recombinant PapMV VLPs with gp33 and points to eExhibit I, representing the electron micrograph of the recombinant and wild type PapMV VLP. In points 14-19, Dr. Leclerc discloses proliferation of gp33-specific T cells induced by DCs pulsed with papMV-gp33, and points out that no

proliferation was observed with control PapMV only, and that PapMV-gp33 results in 256-fold increase in efficiency over the gp33 peptide alone. Dr. Leclerc further discloses generation of gp33 peptide specific T cells, as shown by tetramer staining in exhibit III, due to immunization of mice with PapMV-gp33.

- In response, the Office acknowledges and agrees that PapMV-gp33 has the ability to induce cellular immune responses, especially as it was shown in Exhibit III. Even though the figure in Exhibit II does not show a significant difference between gp33 peptide alone and 1ug PapMV-gp33, the explanation by Dr. Leclerc in point 14, regarding the differences in the amount of the peptide alone and peptide fused with PapMV VLP is considered and taken into account thereby making the results convincingly significant.

- In points 12-13, the Dr. Leclerc states " The ability of PapMV-gp33 to stimulate production of cytotoxic T-lymphocytes in vitro and in vivo was tested by Dr. Alain Lamarre (...), (see Stroni et al. (...))."
  - In response, the Office has considered the cited references. However, in the reference by Storni et al., the gp-33 is fused to a VLP derived from HBcAg and not PapMV. Thus, the reference by Storni et al. does not provide evidence that VLP derived from PapMV-gp33 has the ability to stimulate production of cytotoxic T-lymphocytes in vitro and in vivo.

Applicant has provided experimental results, Exhibit I, II, and III, together with the explanation to the results in Exhibit II, which considered by one of skill in the art would lead to a

conclusion that PapMV when fused with a CTL epitope such as gp33, has the ability to induce cellular immune responses.

Because the experimental results in Exhibit II and III provide evidence that PapMV-gp33 has the ability to stimulate production of cytotoxic T-lymphocytes and because it is known in the art that the induction of humoral or cellular immune response depends on the specificity of the antigenic epitope that is fused with the VLP, and not the VLP itself, the rejection of claims 20-31, 33-39, and 42 under 35 U.S.C. 112, first paragraph, for failing to comply with the enablement requirement **is withdrawn.**

6. A new enablement rejection is made in view of Applicant's amendments to the claims.

Claims 20-25, 27-30, 32-39, 42, and 43 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claim 20, as currently amended, reads on any antigen, which when administered to an animal together with an effective amount of a PapMV adjuvant, has the ability to potentiate an immune response against the said antigen, wherein the immune response is humoral and/or cellular response.

The person of ordinary skill in the art would be unable to predict that any antigen fused to PapMV adjuvant would have the ability to potentiate a humoral and/or cellular immune response without first identifying the antigen as a B cell or a T cell epitope. In other words the antigen that has not been identified as a B cell or a T cell epitope may not contribute to induction of humoral

or cellular immune responses, with or without PapMV adjuvant. Also, as it was mentioned earlier, it is known in the art that the induction of humoral or cellular immune response depends on the specificity of the antigenic epitope that is fused with the VLP, and not the VLP itself. Amending the claim 20 to recite "A method of potentiating an immune response against a B cell or a T cell antigenic epitope in an animal (...)" would help overcome this rejection.

7. Applicant's arguments and the Inventor's Declaration have been fully considered and are persuasive. Therefore, the rejection of claims 20-31, 33-39, and 42 under 35 U.S.C. 112, first paragraph, for failing to comply with written description requirement **is withdrawn.**

Conclusion

8. Applicant's amendment necessitated the new ground of rejections presented in this Office action, thus **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Agnieszka Boesen whose telephone number is 571-272-8035. The examiner can normally be reached on 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AB

Agnieszka Boesen, Ph.D.
Examiner
8/25/06

Stacy B. Chen 8/25/06

STACY B. CHEN
PRIMARY EXAMINER